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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,135	05/31/2001	Brandon James Yoe	050623.00168	1923

45159 7590 03/30/2010  
SQUIRE, SANDERS & DEMPSEY LLP  
1 MARITIME PLAZA  
SUITE 300  
SAN FRANCISCO, CA 94111

EXAMINER
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NGUYEN, CAMTU TRAN

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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03/30/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/872,135	<b>Applicant(s)</b> YOE ET AL.	
	<b>Examiner</b> Camtu T. Nguyen	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,10-12,21-32 and 73 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-7, 10-12, 21-25, 27-32, 73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Amendment*

This Office Action is responding to applicant's amendment filed on 1/22/2010. Claims 1, 21, and 31 have been amended. Claims 2, 4, 8-9, 13-20, 33-72, and 74-85 have been cancelled. Claim 26 has been withdrawn from consideration.

### *Response to Arguments*

Regarding independent claim 1, applicant remarked that the Hossainy reference does not teach/disclose **a concentration of therapeutic agent that gradually decrease along the length of...**" and that one of ordinary skilled in the art would understood that a **therapeutic agent that gradually decreases** has a less sudden changes inward or at ends of the elongated source.

In response, it is noted that claim 1 recites **an amount or a concentration of therapeutic agent**. Broad interpretation of applicant's OR alternative limitation requires only one of the elements in the OR limitation to exist in the inventive apparatus. Such interpretation of applicant's OR limitation applies to the rest of claim 1. It is also noted that claim 1 does not recite **therapeutic agent that gradually decreases has a less sudden changes inward or at ends of the elongated source**.

Regarding the Hossainy reference applied against claim 1 in the previous Office Action, Figure 2 in the Hossainy illustrates stent ends (250, 260) are inwardly proximal/distal ends of stent, and that variability in surface area can be used to minimize delivery of a radioactive

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therapeutic agent near stent ends (250, 260), shown in Figure 2. Clearly, such disclosure meets the limitations in applicant's claim 1.

Regarding independent claims 6, 21, and 31, applicant remarked that the Hossainy does not teach/disclose radioactive/drug region gradually transitioning from therapeutic level to a non-therapeutic level.

In response, Figures 8 & 9 in the Hossainy reference discloses a decreased amount of radioactive (i.e. an early termination of radioactive 930), is provided near stent ends (950, 960), column 8 lines 10-22. Such disclosure meets applicant's claims 6, 21, and 31.

At least for the reasons presented above, the 102(e) rejection is maintained.

Regarding applicant's remarks against the Hoissany reference under the 103(a) rejection as not prior art under 103(a), in view applicant's statement of common ownership filed on 8/17/2007. Such remarks are persuasive. Thus, such 103(a) rejection has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-7, 10-12, 21-25, 27-32, and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossainy et al (U.S. Patent No. 6,764,505).

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Hossainy et al discloses in Figure 1-9 a stent comprising elements as recited in these claims including a body having a first end and a second end and a middle segment between the first and the second ends, a variable stent surface per unit length of the body wherein the first and the second ends have a lesser surface area than the middle segment, and a drug deposited on the stent so that the first and the second ends have a lesser amount of the drug than the middle segment.

Regarding independent claim 1, Figure 2 in the Hossainy illustrates stent ends (250, 260) are inwardly proximal/distal ends of stent, and that variability in surface area can be used to minimize delivery of a radioactive therapeutic agent near stent ends (250, 260), shown in Figure 2. Clearly, such disclosure meets the limitations in applicant's claim 1.

Regarding independent claims 6, 21, and 31, Figures 8 & 9 in the Hossainy reference discloses a decreased amount of radioactive (i.e. an early termination of radioactive 930), is provided near stent ends (950, 960), column 8 lines 10-22. Such disclosure inherently suggest that near the end of stents (950, 960) is provided with radioactive-free, yielding the stent ends (950, 960) with non-therapeutic level, hence, meets applicant's claims 6, 21, and 31.

Regarding claims 3, 7, the Hoissany reference discloses the elongated source comprises a stent (100), shown in Figure 1.

Regarding claims 5 & 73, Hoissany reference discloses its stent is coated, and that its variability in surface area can be used in minimize delivery of a radioactive therapeutic agent near stent ends (250, 260) in order to avoid sub-threshold radiation delivery & edge restenosis (column 7 lines 24-28), clearly suggesting that the stent has anti-cell proliferation drug delivered along the length of the stent thereon.

Regarding claims 10-12 and 27-29, Hoissany discloses Phosphorous ( $^{32}\text{P}$ ) which is pure beta particles and Palladium (Pd) which is gamma particles (column 6 lines 36-40).

Regarding claims 22 & 32, Figure 6 illustrates radiation dose delivered to the stent & past the proximal/distal end of the stent.

Regarding claims 23-25, see illustration below.

Regarding claims 30, Hoissany discloses an average minimum dose is 20 Gy, within the upper range in claim 30.

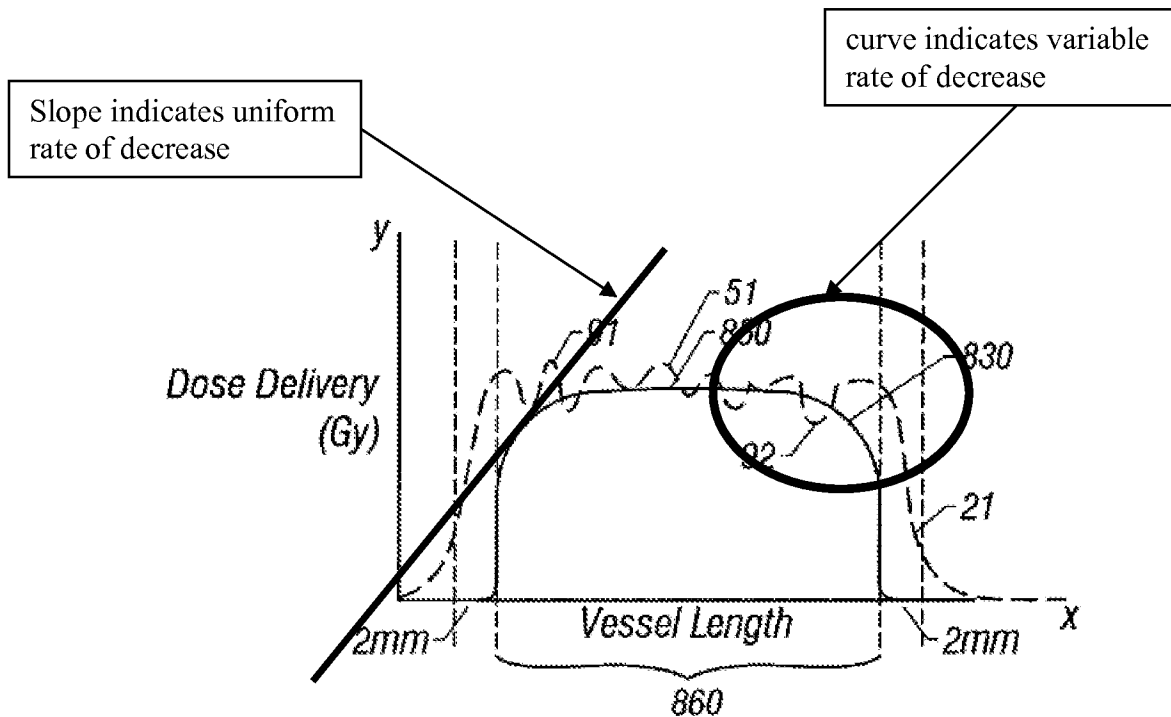


FIG. 8

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/  
Examiner, Art Unit 3772

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772